DDM

Display Date 8-4-04
Publication Date 8-5-04
Certifier A. Corbin

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0383]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Recommended Glossary and Educational Outreach to Support Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Fax written comments on the collection of information by [*insert date 30 days after date of publication in the* **Federal Register**].

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA 250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Recommended Glossary and Educational Outreach to Support Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use

This document provides guidance on the voluntary use of selected symbols in place of text to convey some of the information required for in vitro diagnostic devices (IVDs) intended for professional use under § 809.10 (21 CFR 809.10) (FDA's labeling requirements for IVDs) and parts 610 and 660 (21 CFR parts 610 and 660) (FDA's labeling requirements for biologics (including IVDs)) that are licensed under the Public Health Service Act. Use of these symbols will not result in a new collection of information but is a means of fulfilling underlying labeling requirements that are subject to OMB clearance. Under section 502(c) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 352), a drug or device is misbranded

If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

This guidance document recommends that a glossary of terms accompany each IVD to define the symbols used on that device's labels and/or labeling. Furthermore, this guidance recommends an educational outreach effort to enhance the understanding of newly introduced symbols. Both the glossary and the educational outreach help to ensure that IVD users will have enough

general familiarity with the symbols, as well as quick reference materials available, to be likely to understand the symbols used in IVD labeling, further ensuring that such labeling satisfies the requirements of section 502(c) of the act.

Respondents: The likely respondents are IVD manufacturers who plan to use the selected symbols in place of text on the labels and/or labeling of their IVDs.

In the **Federal Register** of October 28, 2003 (68 FR 61449), FDA published a 60-day notice requesting public comment on the information collection provisions. FDA received one comment regarding information collection from a manufacturer. This comment stated "We believe no additional educational outreach is needed for the symbols contained within the draft guidance document. A user comprehension study was conducted showing acceptance of these symbols and an explanation is provided in the glossary." FDA disagrees with this comment. The educational outreach will enhance the understanding of the newly introduced symbols among the intended audience.

FDA estimates the burden for this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Activity	No. of Respondents	Annual Frequency per Responses	Total Annual Responses	Hours per Response	Total Hours
Glossary	1,742	1	1,742	4	6,9681
Educational outreach	1,742	1	1,742	16	27,872
Total					34,840

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] One-time burden.

The glossary and educational outreach activities would be carried out by domestic and foreign IVD manufacturers. The Center for Devices and Radiological Health Information Retrieval System's Registration and Listing Information database provided the number of IVD manufacturers as 1,742; 1,206 are domestic IVD manufacturers and 536 are foreign manufacturers.

Consequently, FDA has based its burden estimate on the maximum possible number of manufacturers choosing to implement the use of symbols in labeling. The number of hours per response for the glossary and educational outreach activities were derived from consultation with a trade association and FDA personnel. The 4-hour estimate for a glossary is based on the average time necessary for a manufacturer to modify the glossary, as shown in the draft guidance, for the specific symbols used in labels or labeling for the IVDs they manufacture. The 16-hour estimate for educational outreach includes activities manufacturers will use to educate the various professional users of IVDs about the meaning of the IVD symbols. This estimate is based on FDA 's expectation that IVD manufacturers will jointly sponsor many educational outreach activities.

The draft guidance document also refers to labeling requirements, annual reporting requirements, and other information collections established under existing regulations. The collections of information described in section III of the guidance that result from § 809.10 were approved under OMB control number 0910–0485. The collections of information described in section III of the guidance that result from §§ 610.60, 610.61, and 610.62 were approved under OMB control number 0910–0338. In accordance with section 3506(c)(2)(A) of the PRA, a 60-day notice soliciting public comment on the collections of information described in section III of the guidance that result from part 660 (§§ 660.2, 660.28, 660.35, 660.45, and 660.55) published in the **Federal Register** of July 22, 2003 (68 FR 43359). The collections of information described in section X of the guidance, regarding annual reports, were approved under OMB control numbers 0910–0231 and 0910–0315. The

collections of information described in section X of the guidance, regarding adverse event reporting, were approved under OMB control numbers 0910–0437 and 0910–0291.

Dated: 7-27-04
July 27, 2004.

Jeffrey Shuren

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 04–????? Filed ??–??–04; 8:45 am]

BILLING CODE 4160–01–S